

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

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Serial No.: 09/647,475

Confirmation No.: 7111

Filed: August 20, 2001

For: COMPOSITE DEVICES INCORPORATING BIOLOGICAL MATERIAL AND METHODS

Amendments to the Claims

This listing of claims replaces all prior versions, and listings, of claims in the above-identified application:

1. **(Currently amended)** A composite biological device comprising a biostructure comprising at least one biological material as an integral imbedded component within the biostructure,

wherein at least a portion of the biostructure comprises a nonporous latex-derived material and at least a portion of the biostructure comprises a porous latex-derived material having the at least one biological material imbedded therein,

wherein the biological material is metabolically active or becomes metabolically active upon hydration, and

further wherein the biostructure is obtainable by gravure coating, piezo-electric printing, or acoustic printing.

2. **(Currently amended)** A composite biological device comprising a layered biostructure comprising at least one biological material as an integral component within the biostructure, ~~wherein at least a portion of the biostructure comprises a nonporous latex-derived material and wherein the biological material is metabolically active or becomes metabolically active upon hydration,~~

wherein the biostructure comprises:

at least one layer comprising a porous latex-derived material having the at least one biological material imbedded therein, and

at least one layer comprising a nonporous latex-derived material, wherein the biological material is metabolically active or becomes metabolically active upon hydration, and

further wherein the biostructure is obtainable by gravure coating, piezo-electric printing, or acoustic printing.

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3. **(Currently amended)** A composite biological device comprising a biostructure comprising at least one biological material as an integral component within the biostructure, wherein at least a portion of the biostructure comprises a nonporous latex-derived material and at least a portion of the biostructure comprises a porous latex-derived material having the at least one biological material imbedded therein, wherein the biological material is metabolically active or becomes metabolically active upon hydration, wherein the nonporous material defines at least one channel or at least one well, and further wherein the biostructure is obtainable by gravure coating, piezo-electric printing, or acoustic printing.
4. **(Currently amended)** A composite biological device comprising a biostructure comprising at least one biological material as an integral component within the biostructure, wherein at least a portion of the biostructure comprises a nonporous latex-derived material and at least a portion of the biostructure comprises a porous latex-derived material having the at least one biological material imbedded therein, wherein the biological material is metabolically active or becomes metabolically active upon hydration, wherein the biostructure comprises no greater than about 75% by volume biological material, and further wherein the biostructure is obtainable by gravure coating, piezo-electric printing, or acoustic printing.
5. **(Original)** The composite device of claim 4 wherein the biostructure comprises no greater than about 50% by volume biological material.

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6. **(Previously presented)** The composite device of claim 1 wherein the biological material comprises a prokaryote, a eukaryote, an archean organism, or a combination thereof.
7. **(Previously presented)** The composite device of claim 1 wherein the biological material comprises a mammalian cell, a blood cell, an avian cell, a plant cell, an insect cell, a bacteriophage, a spore, a virus, or a combination thereof.
8. **(Previously presented)** The composite device of claim 1 wherein the biological material comprises a recombinant bacterial, yeast, or fungal cell.
9. **(Previously presented)** The composite device of claim 8 wherein the recombinant cell is desiccation tolerant.
10. **(Original)** The composite device of claim 1 wherein the biostructure further comprises at least one additive selected from the group of a salt, a pigment, an adsorbent, a liquid crystal, a porosity modifier, a chelating agent, a nutrient, a surfactant, a dye, a photoreactive compound, an antibiotic, an antimicrobial, a bacteriostatic compound, an enzyme, an osmoprotectant, a biopolymer, a metal, a chemical catalyst, and a combination thereof.
11. **(Currently amended)** ~~[[A]] The composite [[biological]] device of claim 1 comprising a biostructure comprising at least one biological material as an integral component within the biostructure;~~
~~—— wherein at least a portion of the biostructure comprises a nonporous latex-derived material and~~
~~—— wherein the biological material is metabolically active or becomes metabolically active upon hydration; and~~
wherein the biostructure further comprises a transmitter incorporated therein.

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12. **(Currently amended)** ~~[[A]] The composite [[biological]] device of claim 1 comprising a biostructure comprising at least one biological material as an integral component within the biostructure, wherein at least a portion of the biostructure comprises a nonporous latex-derived material and wherein the biological material is metabolically active or becomes metabolically active upon hydration, and wherein the biostructure further comprises a detector incorporated therein.~~

13. **(Original)** The composite device of claim 12 wherein the detector senses a response emitted from the biological material when in contact with an analyte.

14. **(Currently amended)** ~~[[A]] The composite [[biological]] device of claim 1 comprising a biostructure comprising at least one biological material as an integral component within the biostructure, wherein at least a portion of the biostructure comprises a nonporous latex-derived material and wherein the biological material is metabolically active or becomes metabolically active upon hydration, and wherein the biostructure comprises a latex-derived material is cross-linked latex-derived polymer.~~

15. **(Previously presented)** The composite device of claim 1 wherein the biostructure is non-hydrated and the biological material becomes metabolically active upon hydration.

16. **(Cancelled)**

17. **(Currently amended)** The composite device of claim ~~[[16]]~~ 1 wherein the porous latex-derived material comprises a mixture of latices.

18. **(Cancelled)**

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19. **(Currently amended)** The composite device of claim ~~[[18]]~~ 111 wherein the substrate comprises a membrane, a filament, ~~[[or]]~~ a wire, a film, a foam, a metal, a glass, a ceramic, an organic polymer, an electrode, a semiconductor device, or combinations thereof.
20. **(Currently amended)** The composite device of claim ~~[[18]]~~ 111 wherein the substrate comprises a metal or a polymeric material.
21. **(Currently amended)** The composite device of claim ~~[[18]]~~ 111 wherein the substrate is an electronic device.
22. **(Currently amended)** ~~[[A]]~~ The composite ~~[[biological]]~~ device of claim 1 comprising a biostructure comprising at least one biological material as an integral component within the biostructure, wherein at least a portion of the biostructure comprises a nonporous latex-derived material and wherein the biological material is metabolically active or becomes metabolically active upon hydration, and wherein the biostructure comprises wires or electrodes.
23. **(Original)** The composite device of claim 1 wherein the biostructure is no greater than about 500 microns thick.
24. **(Original)** The composite device of claim 1 wherein the entire device is no greater than about 500 microns thick.
- 25-47. **(Canceled)**
48. **(Original)** A method of determining the presence of an analyte in a sample, the method comprises contacting the sample with the device of claim 1, wherein, upon contact with the analyte, the biological material produces a response and emits a signal; and detecting the signal.

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49-99. (Canceled)

100. **(Previously presented)** A method of determining the presence of an analyte in a sample, the method comprises contacting the sample with the device of claim 2, wherein, upon contact with the analyte, the biological material produces a response and emits a signal; and detecting the signal.

101. **(Previously presented)** A method of determining the presence of an analyte in a sample, the method comprises contacting the sample with the device of claim 3, wherein, upon contact with the analyte, the biological material produces a response and emits a signal; and detecting the signal.

102. **(Previously presented)** A method of determining the presence of an analyte in a sample, the method comprises contacting the sample with the device of claim 4, wherein, upon contact with the analyte, the biological material produces a response and emits a signal; and detecting the signal.

103. **(Previously presented)** A method of determining the presence of an analyte in a sample, the method comprises contacting the sample with the device of claim 11 wherein, upon contact with the analyte, the biological material produces a response and emits a signal; and detecting the signal.

104. **(Previously presented)** A method of determining the presence of an analyte in a sample, the method comprises contacting the sample with the device of claim 12 wherein, upon contact with the analyte, the biological material produces a response and emits a signal; and detecting the signal.

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105. **(Previously presented)** A method of determining the presence of an analyte in a sample, the method comprises contacting the sample with the device of claim 14 wherein, upon contact with the analyte, the biological material produces a response and emits a signal; and detecting the signal.

106-107. **(Cancelled)**

108. **(Previously presented)** A method of determining the presence of an analyte in a sample, the method comprises contacting the sample with the device of claim 22 wherein, upon contact with the analyte, the biological material produces a response and emits a signal; and detecting the signal.

109. **(Currently amended)** ~~[[A]] The composite [[biological]] device of claim 1 comprising a biostructure comprising at least one biological material as an integral imbedded component within the biostructure, wherein at least a portion of the biostructure comprises a nonporous latex-derived material and wherein the biological material is metabolically active or becomes metabolically active upon hydration, and further wherein the biostructure comprises a porous sealant layer that does not include biological material.~~

110. **(Currently amended)** A composite biological device comprising a three-dimensional biostructure comprising at least one biological material as an integral, imbedded, permanently trapped, component within the biostructure,

wherein at least a portion of the biostructure comprises a nonporous latex-derived material and at least a portion of the biostructure comprises a porous latex-derived material having the at least one biological material imbedded therein,

wherein the biological material is metabolically active or becomes metabolically active upon hydration, and

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further wherein the biostructure is obtainable by gravure coating, piezo-electric printing, or acoustic printing.

111. (New) The composite device of claim 1 wherein the biostructure is supported on a substrate distinct from the nonporous latex-derived material.

112. (New) A composite biological device comprising a biostructure comprising at least one biological material as an integral imbedded component within the biostructure, at least one porosity modifier, and at least one osmoprotectant,

wherein at least a portion of the biostructure comprises a nonporous latex-derived material and at least a portion of the biostructure comprises a porous latex-derived material having the at least one biological material imbedded therein, and

further wherein the biological material is metabolically active or becomes metabolically active upon hydration.

113. (New) The composite device of claim 112 wherein the porosity modifier is sucrose.

114. (New) The composite device of claim 112 wherein the osmoprotectant is glycerol.

115. (New) A composite biological device comprising a biostructure comprising at least one biological material as an integral imbedded component within the biostructure,

wherein at least a portion of the biostructure comprises a nonporous latex-derived material and at least a portion of the biostructure comprises a porous latex-derived material having the at least one biological material imbedded therein,

further wherein the biological material is metabolically active or becomes metabolically active upon hydration, and

further wherein the device is stable for at least 6 months under ambient conditions.

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116. (New) A method of determining the presence of an analyte in a sample, the method comprises contacting the sample with the device of claim 112 wherein, upon contact with the analyte, the biological material produces a response and emits a signal; and detecting the signal.

117. (New) A method of determining the presence of an analyte in a sample, the method comprises contacting the sample with the device of claim 115 wherein, upon contact with the analyte, the biological material produces a response and emits a signal; and detecting the signal.